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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,275

07/08/2004

Gino F. Morello

021906-019US

5968

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7590

06/14/2006

LOCKE LIDDELL & SAPP LLP

ATTN. DOCKETING

600 TRAVIS, #3400

HOUSTON, TX 77002

EXAMINER

PATEL, NATASHA

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/501,275	Applicant(s) MORELLO, GINO F.	
	Examiner Natasha N. Patel	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18, 20, 22-26, and 28-34 is/are rejected.
- 7) ☒ Claim(s) 16, 17, 19, 21 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Upon further consideration, the examiner has concluded that the claims previously restricted are inseparable for the purposes of restriction. The restriction requirement discussed telephonically with Mr. Mark Gleason on May 25, 2006 has therefore been canceled. All claims pending will now be examined.

Claim Objections

2. Claims 9, 11, 13, 15, 16, 18, and 20 are objected to because of the following informalities: Applicant does not define what "A" represents. Appropriate correction is required.
3. Claims 31 and 34 are objected to because "an pump" should read "a pump." Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6, 7, 24-26, and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Antaki et al. (US Patent 5,888,242).

6. Regarding Claim 1, Antaki discloses a method of detecting ventricular collapse in a patient having a blood pump implanted (see col. 2, lines 14-16), the method comprising: sampling a time-based system parameter of the blood pump (see col. 2, lines 16-18); analyzing the time-based system parameter (see col. 2, lines 34-38); and calculating a suction probability index that provides an indication of the imminence of ventricle collapse (see col. 4, lines 37-41). An index is merely something that indicates or points out. Thus, the examiner considers that blood flow rate serves as a suction probability index because it is an indicator of ventricular collapse.

7. Regarding Claims 2 and 3, Antaki discloses that the time-based system parameter of the blood pump includes sampling the pump current and the pump speed (see col. 1, lines 51-58).

8. Regarding Claim 6, Antaki discloses computing the spectral content of the sampled time-based signal (see col. 3, lines 34-38).

9. Regarding Claim 7, Antaki discloses applying the computed spectral content to a spectral analysis equation to calculate the suction probability index (see col. 3, line 28-col. 4, line 9). The examiner considers that since the spectral content includes current (I) (see col. 5, lines 62-67) and current (I) is used to calculate suction probability index (Q), Antaki's invention meets the claim.

10. Regarding Claims 24-26, Antaki discloses that analyzing the time-based parameter (flow rate) includes calculating the slope, or the first derivative, of the time-based system parameter (see col. 5, lines 61-62). The examiner considers that the derivative is the same as the slope because American Heritage® Dictionary defines

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derivative as “the slope of the tangent line to the graph of a function at a given point” (*The American Heritage® Dictionary of the English Language, Fourth Edition*). Antaki further discloses that calculating the suction probability index includes comparing the slope to a predetermined value (see col. 5, lines 64-65 and Figure 5).

11. Regarding Claim 28, Antaki discloses a control system for an pump system, the control system comprising: a processor (microprocessor 20) having inputs for receiving a signal representing a time-based parameter of the pump system (see col. 4, lines 8-9); the processor being programmed to analyze the time-based system parameter and calculate a suction probability index that provides an indication of the imminence of ventricle collapse (see col. 4, lines 21-24 and lines 37-41).

12. Regarding Claim 29, Antaki discloses that the time based parameter includes the pump system current (see col. 4, lines 21-24).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 4, 5, 23, and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antaki et al. (US Patent 5,888,242) in view of Benkowski et al. (US Patent 6,183,412).

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15. Regarding Claims 4, 30, and 33, Antaki discloses that sampling a time-based system parameter of the blood pump includes sampling the flow rate (see col. 2, lines 61-64). Antaki does not explicitly disclose a flow-sensing device providing an indication of the flow rate through the pump. Benkowski discloses a flow sensor (see col. 12, lines 1-13). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a flow sensor into Antaki's pump because it eliminates the extra step of having to derive it from the pump current and speed and because Benkowski teaches the importance of having a flow sensor in a VAD system (see col. 12, lines 23-27).

16. Regarding Claim 5, Antaki does not disclose converting the time-based parameters to digital signals. However, digitizing signals is a common and well-known step in the signal processing art. For example, Benkowski discloses converting the sampled time-based parameter to a digital signal (see A/D converter, col. 9, lines 7-12). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to convert the time-based parameters into digital signals in order to make the signals easier to store and process.

17. Regarding Claim 23, Antaki does not elaborate on the signal processing techniques. Although Antaki does not disclose a switched-capacitor filter, it would have been obvious by those of ordinary skill in the art at the time of the invention to use some type of filter. The applicant does not disclose any criticality in the use of a switched-capacitor filter over any other filter, such as a loop filter or a Butterworth filter. Benkowski discloses filtering the sampled time-based parameter signals (see col. 15,

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lines 20-22). Thus, it would have been a matter of obvious design choice by anyone looking to avoid distortion based on temperature change to use a switched-capacitor filter.

18. Regarding Claims 31 and 34, Antaki discloses a pump (blood pump 12). Antaki also discloses a motor controller (speed stabilizing circuit) coupled to the motor; a rotor (see col. 1, lines 60-61); a processor (microprocessor 20) having inputs coupled to the motor controller for receiving a signal representing a time-based parameter of the pump (see col. 4, line 24); the processor being programmed to analyze the time-based system parameter and calculate a suction probability index (see col. 4, line 39) that provides an indication of the imminence of ventricle collapse (see col. 4, lines 23). Antaki does not disclose that the pump includes a stator. However, it is well known and common for a rotary pump. Nevertheless, Benkowski discloses a similar pump (blood pump 12) with a motor controller (motor controller 84) coupled to a motor (motor 38), a rotor (rotor 42), and a stator (stator 40), including a plurality of stator windings (windings 52). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a stator into Antaki's pump because Antaki's pump is also a rotary pump and needs something stationary about which the rotor can turn

19. Regarding Claim 32, Benkowski discloses that the motor controller applies current to the stator windings in a sequence to create a rotating field (see col. 6, lines 22-26); and wherein the time-based parameter includes the stator winding current (see col. 6, lines 20-22). The examiner considers that the motor controller is equivalent to the

processor because both receive current, which can then be used to detect a ventricular collapse (see col. 9, lines 18-23).

20. Claims 8, 10, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antaki et al. (US Patent 5,888,242) and Benkowski et al. (US Patent 6,183,412), further in view of Schnetzka et al. (US Patent 4,499,534).

21. Regarding Claims 8 and 10, Antaki does not disclose computing distortion. Benkowski discloses distortion (see col. 9, lines 23-26). Antaki and Benkowski do not elaborate on the type of distortion computed. Schnetzka discloses total distortion, which includes harmonic distortion, noise, and other transients (see col. 13, lines 22-31). The examiner considers that in order to eliminate the distortion from the signal, some type of computation must occur in order to determine how much of the signal is owed to distortion and should be filtered out. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the distortion described by Schnetzka into consideration in order to clean up the signals obtained by Antaki and provide an accurate indication of the imminence of ventricular collapse.

22. Regarding Claims 12 and 14, Antaki and Benkowski do not elaborate on the distortion above and below the fundamental frequency. Schnetzka discloses filtering the signal above and below the fundamental frequency (see col. 13, lines 22-31). The examiner considers that computing distortion is integral to the filtering process because one must figure out what parts of the signal are due to unnecessary interference to derive the real signal, or the signal that carries physiological importance. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to

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compute the distortion above and below the fundamental frequency because Schnetzka describes that filtering the signal in the frequencies surrounding the fundamental frequency is necessary to clean up the signal.

23. Claims 9, 11, 13, 15, 18, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antaki et al. (US Patent 5,888,242)

24. Regarding Claims 9, 11, 13, 15, 18, 20, and 22, Antaki discloses that computing the spectral content includes applying a Fourier Transform (see col. 6, lines 32-37). Although Antaki does not use the same equations as the applicant to calculate the suction probability index, Antaki still incorporates a fundamental frequency and maximum amplitude into the spectral analysis (see col. 5, lines 15-25). The examiner considers that the particular analytical tool used to process a signal would be a matter of design lacking any criticality by the applicant. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use any equation relating fundamental frequency and maximum amplitude because the equation is aiming to achieve the same goal as the applicant—detecting imminent ventricular collapse.

Allowable Subject Matter

25. Claims 16, 17, 19, 21, and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
6/2/06


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766